

**Remarks**

Upon entry of this amendment, claims 1-23 will be pending in the application. Claim 7 is amended to make idiomatic revisions and to recite certain embodiments of compounds according to claim 1 (including in which one or two of  $Z_1$ ,  $Z_2$ ,  $Z_3$ ,  $Z_4$  and  $Z_5$  are independently  $CR^{1a}$  and the remainder are CH;  $U = SO_2$ ); other embodiments of original claim 7 now appear in new claims 12-15. Claim 9 and 11 are amended as discussed herein. New claims 12-23 are added. New claims 12-15 recite certain embodiments of compounds according to claim 1 (one or two of  $Z_1$ ,  $Z_2$ ,  $Z_3$ ,  $Z_4$  and  $Z_5$  are independently  $CR^{1a}$  and the remainder are CH; and  $U = CO$  or  $CH_2$ ; or one of  $Z_1$ ,  $Z_2$ ,  $Z_3$ ,  $Z_4$  and  $Z_5$  is N, one is  $CR^{1a}$  and the remainder are CH; and  $U = CH_2$  or  $SO_2$ ). New claims 16-19 and 20-23 depend from new claims 12-15 and are drawn to pharmaceutical compositions and methods of treating bacterial infections, respectively. These new claims find support in original claims 7-10 and throughout the specification. No new matter is being added.

In the specification, the title of Example 2 is being amended. This finds support at page 6, line 27 of the specification. Furthermore, from an examination of the NMR spectrum it can be seen that the compound is consistent with 4-oxo rather than 3-oxo:

Through the use of  $^1H$  NMR predictor software on the 4-oxo-benzothiazepine moiety, the protons at C2 and C3 are predicted to be multiplets in the 2-2.5 ppm range. By contrast, in the 3-oxo-benzothiazepine moiety (which has possible keto and enol tautomeric forms), the C2 and C4 protons would not be in the range in the  $^1H$  NMR, and are predicted to be at  $>3.5$  ppm.

Looking at the experimental NMR data given for Example 2, there are 3  $CH_2$  groups below 3 ppm. This is consistent with the C2 and C3  $CH_2$  groups of the 4-oxo isomer. The third  $CH_2$  reported is for the  $CH_2$  in the center of the propyldiamine chain at the center of the molecule. Furthermore, for the 3-oxo, one would expect to see a singlet for the  $CH_2$  between the sulfur and carbonyl, which is not present in the NMR data listed for the compound. There is only one singlet reported which is for the methoxy group that integrates to 3 protons.

**Rejection under 35 USC 112, 1<sup>st</sup> paragraph**

On pages 2-7, the Examiner rejects claims 9 and 11 under 35 USC 112, 1<sup>st</sup> paragraph. The Examiner states that the specification is enabling for a method of treating a bacterial infection due to Gram-positive organisms selected from *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*,

Streptococcus pyogenes, Enterococcus faecalis, Enterococcus faecium, and Gram-negative organisms selected from Haemophilus influenzae, E. coli, and Moraxella catarrhalis Ravasio. However, the Examiner posits that the specification does not reasonably provide enablement for a method of treating bacterial infections generally.

Solely to advance prosecution, Applicants have amended claim 9 and 11 to recite the organisms Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Enterococcus faecalis, Enterococcus faecium, Haemophilus influenzae, E. coli, and Moraxella catarrhalis. Support for this amendment is found in the specification at page 17, line 19 to page 18, lines 1-3. Applicants reserve the right to pursue the canceled subject matter in a continuing application.

Applicants respectfully submit that one skilled in the art would be able to make and use the invention of claims 9 and 11 as amended, as well as new claims 20-23, without undue experimentation. Reconsideration and withdrawal of the rejection is respectfully requested.

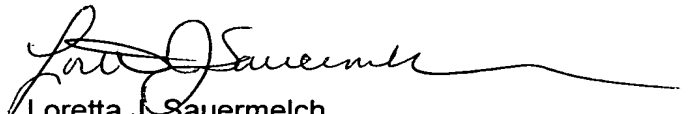
Allowable Subject Matter

On page 7 of the Office Action claims 1-8 and 10 are allowed. Applicants thank the Examiner for indicating allowable subject matter in the application. It is believed that each of the claims as presently amended are in condition for allowance.

Conclusion

Each of the issues raised by the Examiner has been addressed. The application is believed to be in condition for allowance, and a Notice of Allowance in the next Office Action is earnestly solicited.

Respectfully submitted,



Loretta J. Sauermelch  
Attorney for Applicants  
Registration No. 37,347

GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939  
Phone (610) 270-6854  
Facsimile (610) 270-5090  
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